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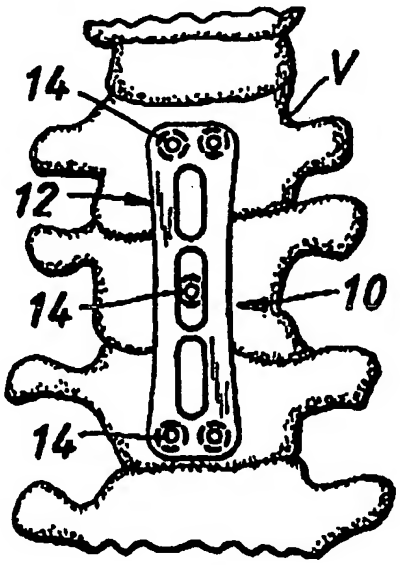
(54) Title: OSTEOSYNTHESIS APPARATUS

(57) Abstract

A bone fixation apparatus (10) having an elongated plate member (12) with at least two pairs of circular openings (24, 26) and at least one elongated slot (28) positioned along the longitudinal axis of the plate member (12). The plate member (12) is formed so as to include a curve in the transverse plane (TP). The openings and slot each form a cavity with walls extending between the upper and lower plate member surfaces (16, 18) with smaller diameter wall portions (32) at the plate member upper and lower surfaces and a larger diameter wall portion (34) therebetween. The openings (24, 26) and slot (28) are shaped to allow for angulation of an implanted bone screw (14). A plurality of bone screws (14) have a threaded first end portion (36) adapted for implantation into a patient's bone mass and a spherically shaped enlarged second end portion (40). A locking member (48) connects to the second end portion (40) to grip the cavity wall of the plate member (12) so as to lock each bone screw (14) into a selected position within the openings (24, 26) and slot (28) of the plate member (12).



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OSTEOSYNTHESIS APPARATUS

The present invention relates to an improved bone or spinal fixation apparatus in the form of an elongated plate member and a locking bone screw. The apparatus has particular utility in anterior cervical spine fixation by providing a plate that allows for angulation of the bone screws and a locking bone screw that secures the bone screws into the plate member at a selected angle corresponding to a thick region of the bone mass.

There are a number of surgical procedures which require fixation of portions of the spine with respect to one another. Typically, bone screws are employed in the fixation of the spine where the implantation of the bone screws is a surgical procedure in which one or more surgical openings are formed in adjacent portions of the spine and threaded bone screws are implanted into the surgical openings. Connective structures such as rods or plates extend between the various spine members and are connected to the spine members by the implanted bone screws.

In the treatment of spinal disorders and spinal fractures, both a posterior and an anterior approach is used and the use of plating systems for posterior internal fixation of the spine is well known. Several plating systems have also been developed for anterior internal fixation of the spine. For example, the Syracuse I-plate provides a number of differently-sized I-shaped plates which are engaged across the vertebrae. A contoured anterior spinal fixation plate is known which includes a number of screw openings through the contoured plate. The number of openings simply provide different locations for engaging a bone screw to the vertebrae, and does not allow for angulation of the bone screws. A further problem with the application of a spinal fixation system is the placement of

such a system in the cervical region where anatomical fit and the lack of bone mass is a problem.

Even with these known posterior and anterior plate fixation systems, there remains a need for a plate and screw system that allows for variation in screw placement along the longitudinal axis of the plate as well as providing for angulation in both the medial-lateral and the cephalad-caudal plane. There is also a need for a fixation system that provides a locking bone screw mechanism for securely fastening the bone screw in the angled position within the plate. There is further a need for a fixation plate that is curved to fit the contours of the vertebrae and is also somewhat bendable during implantation but rigid enough to allow fusion to take place after implantation.

It is thus an object of the present invention to provide a bone fixation system that offers a strong and stable construct for maximum fusion augmentation of any bone structure and yet is versatile enough for any patient and is easy to use.

According to the present invention a bone fixation apparatus comprises a plate member having a longitudinal axis, upper and lower surfaces, opposed longitudinal side edges, at least two pairs of circular openings and at least one elongated slot positioned along the longitudinal axis of the plate member, said openings and slot each forming a cavity extending between the upper and lower plate member surfaces wherein at least some of said cavities are narrower at the plate member upper and lower surfaces than at a plane located between said surfaces, said openings and slot being shaped to allow for transverse and longitudinal angulation of an implanted bone screw; a pluality of bone screws each having a threaded first end portion adapted for implantation into a patient's

bone mass and an enlarged second end portion; and locking means associated with the second end portion of each bone screw for expanding the second end portion to grip a cavity wall of the plate member and for locking each bone screw into a selected position within at least some of the openings and/or slot of the plate member.

The present invention provides an apparatus that can be made small enough for anterior cervical spine applications and is preferably of a size which is suitable to be placed on adjoining vertebrae, the desired size being selected to suit the particular intended application of the apparatus. The plate is preferably curved in the transverse plane.

The distance between the opposed longitudinal side edges is preferably less in the central region of the plate member than in the end regions of the plate so that, for example, the edges are of concave appearance. The upper and/or lower surfaces edges of the openings and slot may advantageously be bevelled.

The bone screw has an enlarged second end which is shaped preferably to allow engagement between that end of the screw and the side walls of a cavity in a bone fixation plate member upon operation of the locking means. A particularly suitable screw has an enlarged second end which is spherically shaped or part-spherical. The locking means preferably is adapted to cause an interference fit between the enlarged second end of the screw and the walls of a cavity and preferably comprises a locking member which is of a size and shape to fit into a bore located in the second end of the bone screw. In a preferred embodiment the second end has a central bore which has threads and at least two radial slits which intersect the bore. In this form the locking means may comprise a threaded

locking member which may be screwed into the central bore thereby to expand the second end portion at the radial slits.

According to the invention a plate member which is adapted for use in a bone fixation apparatus has upper and lower surfaces, a longitudinal axis, opposed longitudinal side edges, two pairs of circular openings and at least one elongated slot positioned along the longitudinal axis of the plate member, said openings and slot each forming a cavity extending between the upper and lower plate member surfaces wherein at least some of said cavities are narrower at the plate member upper and lower surfaces than at a plate located between said surfaces, said openings and slot being shaped to allow for transverse and longitudinal angulation of an implanted bone screw.

According to the invention, a bone screw capable of being locked into a selected position in a plate member comprises a threaded first end portion, a bone screw capable of being locked into a selected position in a plate member, comprising a threaded first end portion adapted for implantation into a patient's bone mass and an enlarged second end portion; and locking means associated with the second end portion of the bone screw for expanding the second end portion to grip portions of a wall surface of an opening in a plate member and for locking the bone screw into a selected position within said opening of a plate member.

For a further understanding of the nature and objects of the present invention, reference should be made to the following detailed description, which is given only as an example of the invention, taken in conjunction with the accompanying drawings, in which like parts are given like reference numbers, wherein:

Figure 1 is an anterior view of the preferred embodiment of the apparatus of the present invention illustrating its placement on the anterior cervical bone tissue;

Figure 2 is a plan view of the preferred embodiment of the apparatus of the present invention illustrating a plate member;

Figure 3 is a side view of the plate shown in Figure 2;

Figure 4 is a sectional view of a portion of the plate shown at lines 4-4 of Figure 2;

Figure 5 is a sectional view of a portion of the plate shown at lines 5-5 of Figure 2;

Figure 6 is a partial sectional view of the plate shown at lines 6-6 of Figure 2;

Figure 7 is a front view of the preferred embodiment of the apparatus of the present invention illustrating a locking bone screw;

Figure 8 is a front view of the preferred embodiment of the apparatus of the present invention illustrating a locking member that connects to the bone screw of Figure 7;

Figure 9 is a top view of the bone screw of Figure 7 with the locking member of Figure 8 in its locked position;

Figure 10 is a fragmentary sectional view of the preferred embodiment of the apparatus of the present invention illustrating the bone screw of Figure 7 placed in an angled position;

Figure 11 is a fragmentary sectional view of the preferred embodiment of the apparatus of the present invention illustrating a longitudinal range of angulation of an implanted bone screw;

Figure 12 is a fragmentary sectional view of the preferred embodiment of the apparatus of the present invention illustrating a transverse range of angulation of an implanted bone screw.

FIG. 1 shows a preferred embodiment of the bone fixation apparatus of the present invention, designated generally by the numeral 10, implanted on the anterior side of cervical vertebrae V of a human patient. The bone fixation apparatus 10 includes a plate member 12 and locking bone screws 14. The plate 12, as shown in FIG. 2, is an elongated plate member 12 having a longitudinal axis LA and upper and lower surfaces 20, 22. The plate member 12 has opposed longitudinal side edges 20-22, first and second ends 23, 25 and a center portion 21. The center portion 21 preferably has a generally smaller width in relation to a larger width at the first and second ends 23, 25. Plate member 12 has a transverse plane TP (FIG. 2) with the plate member 12 being curved along the transverse plane TP. The radius of the transverse curve cross-section is between about 7/8" to 2" and is illustrated in FIGS. 4 and 5. As shown in FIG. 3, the plate member 12 is generally flat along the longitudinal axis LA.

The plate member 12 includes a pair of circular openings 24 positioned at its first end 23 and a second pair of circular openings 26 positioned at its second end 25. At least one elongated slot 28 is positioned along the longitudinal axis LA of the plate member 12, and in a preferred embodiment three elongated slots 28 are positioned along the longitudinal axis LA of the plate member 12. The circular openings 24, 26 and elongated slots 28 have a central

vertical axis CA, as illustrated in FIGS. 4 and 5. In an alternative embodiment, more than two pairs of circular openings can be placed on the ends of the plate member 12.

The openings 24, 26 and the elongated slots 28 of the plate member 12 each form a cavity 30 with angled walls 31 extending between the upper and lower plate member surfaces 16, 18. The cavities 30 are narrower at the upper and lower surfaces 16, 18 of the plate than at an intermediate location 34. The diameter of the wall portions 32 are larger at the upper surface 16 than the diameter of the wall portions 32 at the lower plate surface 18, but the diameter of the wall portions 34 is always larger than that at both the upper and lower surfaces 16, 18. The slightly smaller diameter of the wall portions 32 at the lower surface 18 of the plate member 12 keeps the bone screw 14 from slipping through the cavities 30 prior to insertion of the locking member 48 into the central bore 42 of the bone screw 14. The angulation of the wall surfaces 31 between the upper and lower plate surfaces 16, 18 is generally about between 110° to 160°. The cavities 30 of the openings 24, 26 and slots 28 are shaped to allow for a transverse angulation of generally up to about 35° in both directions from the central vertical axis CA of the openings 24, 26 and slots 28 (FIG. 12). The cavities 30 of the openings 24, 26 are shaped to allow for a longitudinal angulation of generally up to about 35° in both directions from the central vertical axis of the openings 24, 26 (FIG. 12). The cavities 30 of the slots 28 are shaped to allow for a longitudinal angulation of generally between 0° to 130° in both directions from the central vertical axis of the slots 28 (FIG. 11). The openings 24, 26 and slots 28 have a bevelled surface 15 on the upper and lower plate surfaces 16, 18 as illustrated in FIGS. 4-6.

The geometry of the plate member 12, plus the load factors of the openings 24, 26 and slots 28, allow the plate member 12 to be somewhat bendable during implantation while still maintaining the rigidity needed for adequate fixation and immobilization of the vertebrae. Additionally, the transverse curve of the plate member 12 allows it to more closely fit the contours of the vertebrae.

The bone screw 14 has an elongated shank 36, a lower tip 37, and an enlarged upper portion 40 affixed to one end of the shank 36. The lower tip 37 of the bone screw 14 communicates with a helical thread 38 that begins at the lower tip 37 and terminates at the upper portion 40. The enlarged upper portion 40 has a spherically-shaped outer surface 41, a tapered central bore 42 and upper walls 43. The upper walls 43 of the enlarged portion 40 have at least 2 radial slits 44 intersecting the bore 42, and in a preferred embodiment, four radial slits 44 intersecting the bore 42, as seen in FIG. 9. The central bore 42 includes internal threading 46 on a portion of the frustoconical surface 45, as illustrated in FIGS. 7 and 10. The spherically-shaped surface 41 of the upper portion 40 interfaces with the cavities 30 of the openings 24, 26 and elongated slots 28 (see FIG. 10) as will be described more fully hereinafter.

A locking member 48, as shown in FIG. 8, has lower and upper portions 50, 52 respectively and a top surface 51, with the locking member 48 being sized and shaped to fit into the tapered central bore 42 of the bone screw 14. The locking member 48 includes external threading 54 on its lower portion 50 which engages the corresponding internal threading 46 of the central bore 42. A tool receptive socket such as hexagonal socket 56 (FIG. 9) is provided on the flat top surface 51, so that the locking member 48 can be rotated using an allen wrench or other such tool or instrument. When locking member 48 is threaded into the central bore 42 of

bone screw 14, the upper walls 43 expand outwardly further enlarging the upper portion 40.

As shown in FIGS. 10-12, the angular shape of the cavity walls 31 allows for both transverse and longitudinal angulation of an implanted bone screw 14. The spherically-shaped surface 41 allows the upper portion 40 of the bone screw 14 to be freely rotatable within the plate member cavity 30 prior to insertion of the locking member 48. After the bone screws 14 have been positioned within the openings 24, 26 and slots 28 of the plate member 12 and implanted in the vertebrae of a patient, the locking members 48 are threaded into the tapered central bore 42 of the bone screws 14. The threading 54 of the locking member 48 engages the threading 46 of the central bore 42 and the radial slits 44 allow the upper wall portions 43 to expand outwardly as the locking member 48 is tightened into the central bore 42 (FIG. 9).

The expanding wall portions 43 grip the cavity walls 31 so as to lock each bone screw 14 into a selected position within the openings 24, 26 and slots 28 of the plate member 12 as illustrated in FIGS. 11 and 12. The locking mechanism between the plate member 12 and the bone screws 14 prevents the implanted bone screws from backing out of the vertebrae. This locking mechanism, plus the geometry of the plate member 12 allows the bone fixation apparatus 10 to provide a rigid construct when initially implanted. However, as the implanted bone screws loosen over time, the bone fixation apparatus 10 becomes semi-rigid and provides a construct that is somewhat flexible and compliant. During implantation, the configuration of the openings 24, 26 provides secure fixation at the ends of the plate member 12 while the slots 28 provide for a variation in screw placement along the longitudinal axis of the plate member 12. The bone fixation apparatus 10 can be sized to be

used on cervical or lumbar vertebrae in either an anterior or posterior location. The bone fixation apparatus 10 can also be sized to be used on other bone surfaces in addition to vertebrae.

Although the present invention has been described with reference to its preferred embodiments, those skilled in the art will recognize changes which may be made in form or structure which do not part from the spirit of the invention already described in the specification and embodied in the claims which follow.

CLAIMS

1. A bone fixation apparatus, comprising:

a) a plate member having a longitudinal axis, upper and lower surfaces, opposed longitudinal side edges, at least two pairs of circular openings and at least one elongated slot positioned along the longitudinal axis of the plate member;

b) said openings and slot each forming a cavity extending between the upper and lower plate member surfaces wherein at least some of said cavities are narrower at the plate member upper and lower surfaces than at a plane located between said surfaces, said openings and slot being shaped to allow for transverse and longitudinal angulation of an implanted bone screw;

c) a plurality of bone screws each having a threaded first end portion adapted for implantation into a patient's bone mass and an enlarged second end portion; and

d) locking means associated with the second end portion of each bone screw for expanding the second end portion to grip a cavity wall of the plate member and for locking each bone screw into a selected position within at least some of the openings and/or slot of the plate member.

2. An apparatus as claimed in claim 1, wherein said enlarged second end portion of said bone screws is spherically or part-spherically shaped.

3. An apparatus as claimed in either claim 1 or claim 2, wherein said locking means is adapted to form an interference fit between said second end of said bone screw and a cavity wall of a slot or opening.

4. An apparatus as claimed in any of the preceding claims, wherein the second end portion of each bone screw has a tapered central bore and at least two radial slits intersecting the bore, said central bore including threading on a portion of a surface of the bore.

5. The apparatus of claim 4, wherein each bone screw has four radial slits intersecting the bore.

6. An apparatus as claimed in claim 4, wherein the locking means is sized and shaped to fit into the central bore of each bone screw and has threading on a portion of its surface for engaging the threading on the surface of the bore.

7. An apparatus as claimed in any of the preceding claims, wherein said plate member has a transverse plane and is formed so as to include a curve in the transverse plane.

8. An apparatus as claimed in any of the preceding claims, wherein the plate member further includes a plurality of elongated slots positioned along the longitudinal axis of the plate member.

9. An apparatus as claimed in any of the preceding claims, wherein the plate member has a first end, a second end and a center portion and the distance between said opposed longitudinal side edges is smaller in the region of the center portion than in the region of the first and second ends.

10. An apparatus as claimed in any of the preceding claims, wherein one pair of circular openings is positioned near a first end of the plate member and a second pair of circular openings is positioned near a second end of the plate member.

11. An apparatus as claimed in any of the preceding claims, wherein the openings and slot(s) allow for transverse angulation of said bone screw of up to about 35° in each direction from the central vertical axis of the openings and slot.

12. An apparatus as claimed in any of the preceding claims, wherein the openings allow for longitudinal angulation of up to about 35° in each direction from the central vertical axis of the openings.

13. An apparatus as claimed in any of the preceding claims, wherein the slot(s) allow(s) for longitudinal angulation from about 0° to 130° from the central vertical axis of the slot.

14. An apparatus as claimed in any of the preceding claims, wherein the openings and slot include a bevelled surface on at least one of the upper and lower surfaces of the plate member.

15. An apparatus as claimed in any of the preceding claims, wherein the plate member is of a suitable size to be placed on adjoining cervical vertebrae.

16. An apparatus as claimed in any of the preceding claims, wherein the plate member is of a suitable size to be placed on adjoining lumbar vertebrae.

17. An apparatus as claimed in any of the preceding claims, wherein the plate member is of a suitable size to be placed on an anterior side of the cervical vertebrae.

18. A plate member, adapted for use in a bone fixation apparatus, having upper and lower surfaces, a longitudinal axis, opposed

longitudinal side edges, two pairs of circular openings and at least one elongated slot positioned along the longitudinal axis of the plate member;

b) said openings and slot each forming a cavity extending between the upper and lower plate member surfaces wherein at least some of said cavities are narrower at the plate member upper and lower surfaces than at a plate located between said surfaces, said openings and slot being shaped to allow for transverse and longitudinal angulation of an implanted bone screw.

19. A plate member as claimed in claim 18, having a transverse plane and being formed so as to include a curve in the transverse plane.

20. A plate member as claimed in either claim 18 or claim 19, wherein the plate member includes a plurality of elongated slots positioned along the longitudinal axis of the plate member.

21. A plate member as claimed in any of claims 18 - 20, wherein the plate member has a first end, a second end and a center portion and the distance between said opposed side edges is smaller in the region of the center portion than in the region of the first and second ends.

22. A plate member as claimed in any of claims 18-21, wherein one pair of circular openings is positioned near a first end of the plate member and a second pair of circular openings is positioned near the second end of the plate member.

23. A plate member as claimed in any of claims 18 - 22, wherein the openings and slot(s) allow for transverse angulation of said

bone screw of up to about 35° in each direction from the central vertical axis of the openings and slot.

24. A plate member as claimed in any of claims 18 - 23, wherein the openings allow for longitudinal angulation of up to about 35° in each direction from the central vertical axis of the openings.

25. A plate member as claimed in any of claims 18 - 24, wherein the slot(s) allow(s) for longitudinal angulation from about 0° to 130° from the central vertical axis of the slots.

26. A plate member as claimed in any of claims 18 - 25, wherein the openings and slot(s) include a bevelled surface on at least one of the upper and lower surfaces of the plate member.

27. A bone screw capable of being locked into a selected position in a plate member, comprising:

a) a threaded first end portion adapted for implantation into a patient's bone mass and an enlarged second end portion; and

b) locking means associated with the second end portion of the bone screw for expanding the second end portion to grip portions of a wall surface of an opening in a plate member and for locking the bone screw into a selected position within said opening of a plate member.

28. A bone screw as claimed in claim 27, wherein said second end portion is spherical or part-spherical.

29. A bone screw as claimed in either claim 27 or claim 28, wherein said locking means is adapted to form an interference fit between said second end of said bone screw and a cavity wall of an opening or slot formed in a plate member.

30. A bone screw as claimed in any of claims 27 - 29, wherein the second end portion has a tapered central bore and at least two radial slits intersecting the bore, said central bore including threading on a portion of a surface of the bore.

31. A bone screw as claimed in claim 30 having four radial slits intersecting the bore.

32. A bone screw as claimed in either claim 30 or claim 31, wherein the locking means is sized and shaped to fit into the central bore of each bone screw and has threading on a portion of the screw's surface for engaging the threading on the surface of the bore.

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FIG. 1.

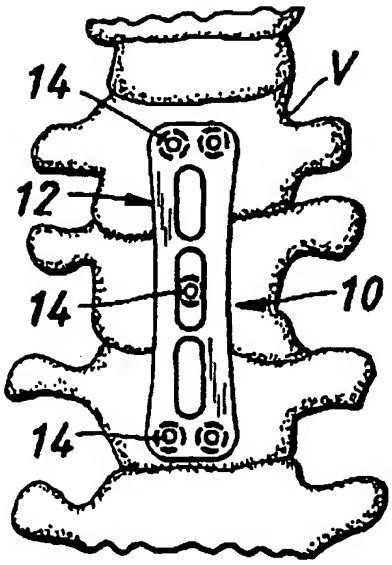


FIG. 2.

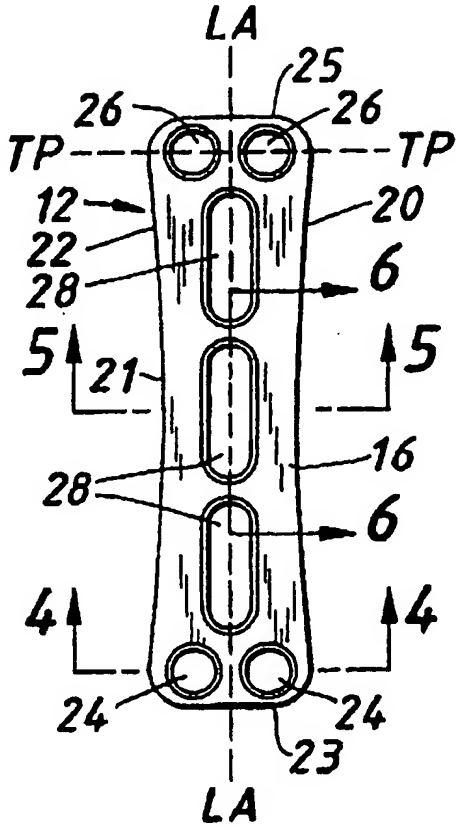


FIG. 3.

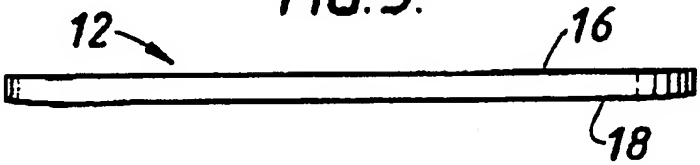
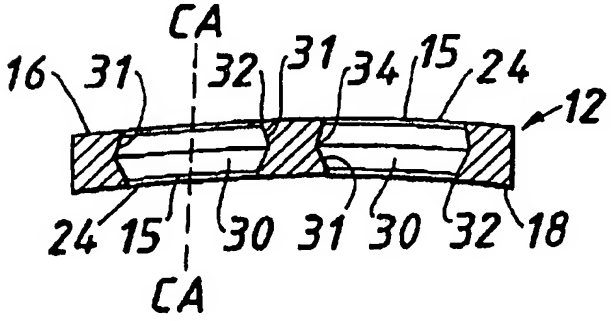


FIG. 4.



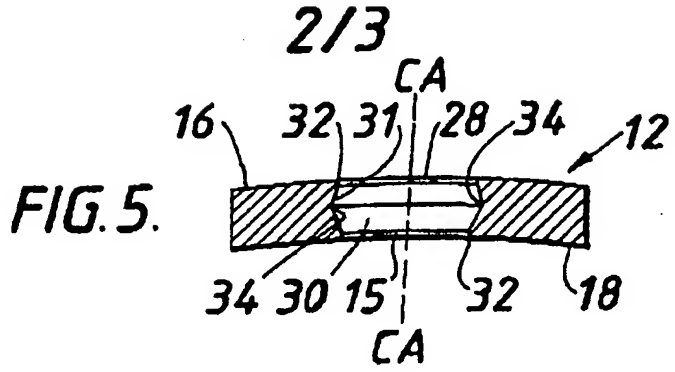


FIG.5.

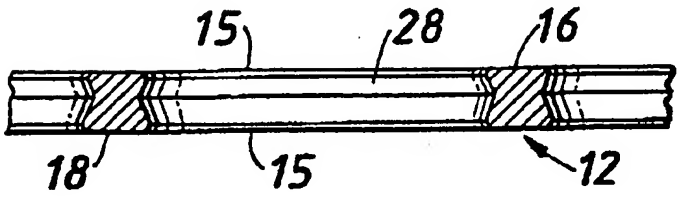


FIG.6.

FIG.7.

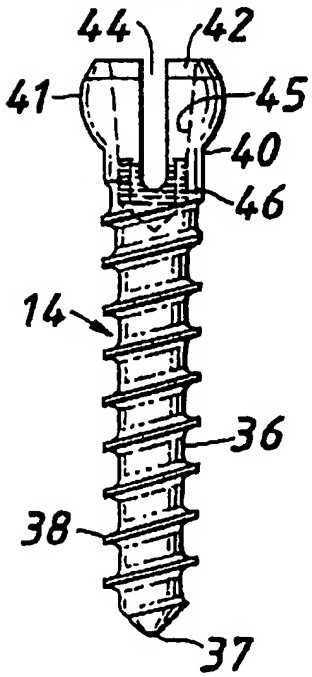


FIG.8.

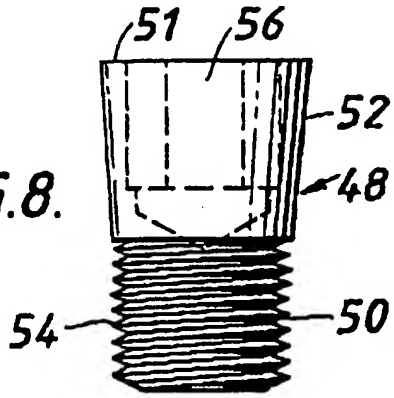
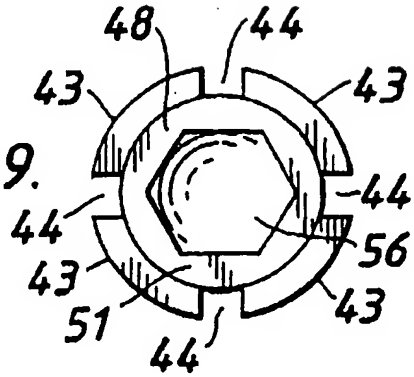


FIG.9.



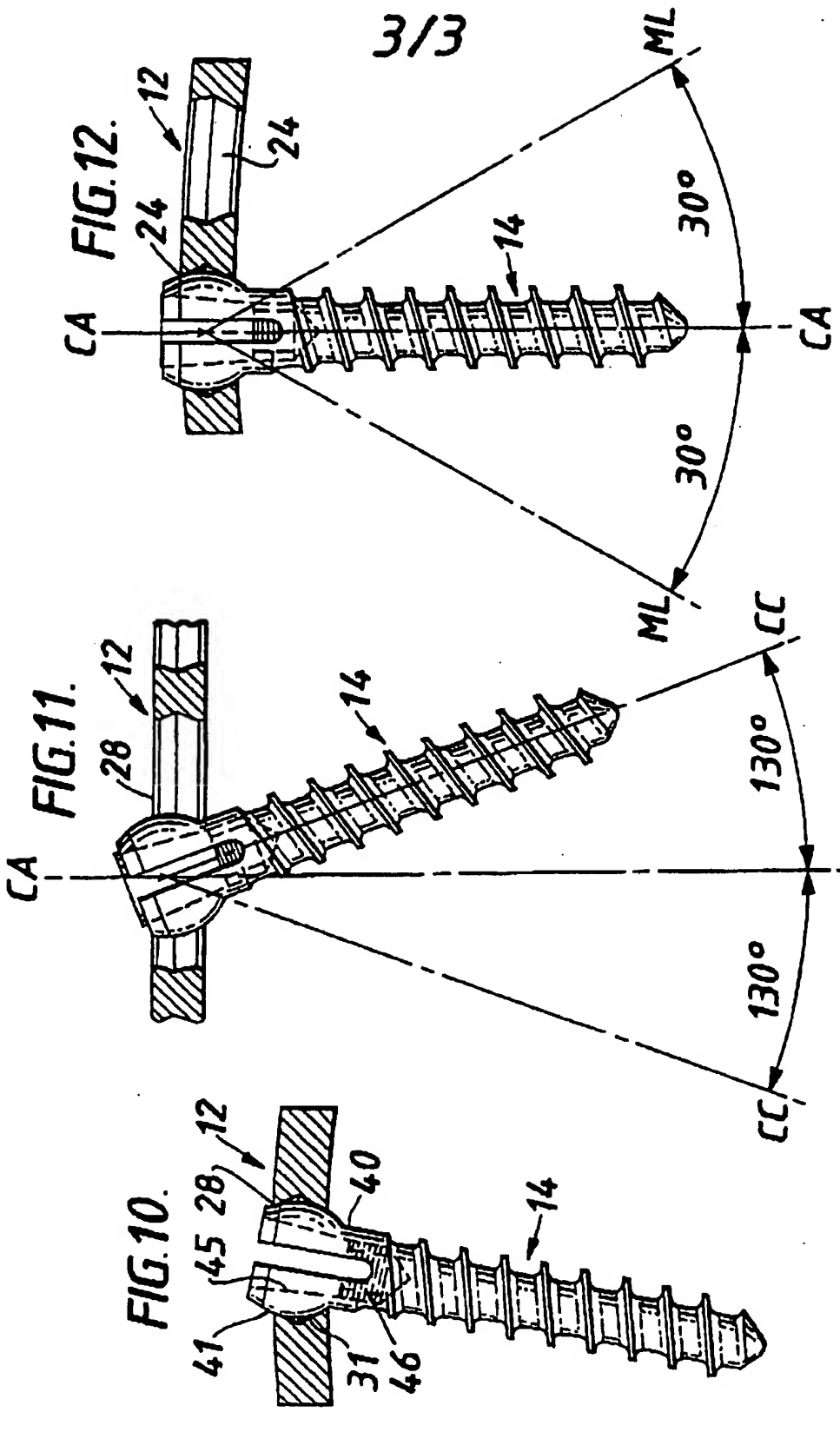


FIG.12.
12
24
24
14
CA
CA
ML
ML
30°
30°
FIG.11.
12
28
14
CA
CA
CC
CC
130°
130°
FIG.10.
12
28
40
45
14
41
31
46

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/11681

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/70, 80, 86
US CL :606/61, 69, 73

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/61, 69-71, 73

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,484,570 (SUTTER ET AL.) 27 November 1984, see entire document.	27-29
Y	WO, A, 88/03781 (RAVEH) 02 June 1988, see entire document.	1-3, 18-20
Y, P	US, A, 5,364,399 (LOWERY ET AL.) 15 November 1994. see entire document	1-3, 18-20
A	US, A, 5,324,290 (ZDEBLICK ET AL.) 28 June 1994.	1-32

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 04 DECEMBER 1995	Date of mailing of the international search report 17 JAN 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer TAMARA L. GRAYSAY Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/11681

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-17, 21-26, 30-32
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.